




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL  
SAFETY AND POLLUTION  
PREVENTION

**MEMORANDUM**

DATE: 5/27/2021

SUBJECT: Efficacy Review for Klorsept, EPA Reg. No. 71847-6, Case #00216556  
Efficacy Review for Klorkleen 2, EPA Reg. No. 71847-7, Case #00216560  
DP Barcode: #460906  
E-Submission: #59654

FROM: Sophie Nguyen, Team Lead   
Efficacy Branch  
Antimicrobials Division (7510P)  
Date Signed: 5/27/2021

TO: Steven Snyderman PM33/Daniel Halpert  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

APPLICANT: Medentech Ltd.  
Whitemill Industrial Estate  
Clonard Road, Wexford, Ireland

**EPA Reg. Nos. 71847-6 & 71847-7**

**FORMULATION FROM LABELS:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Sodium dichloro-s-triazinetriene .....	48.21%*
<u>Other Ingredients</u> .....	<u>51.79%</u>
Total .....	100.00%

\*Equivalent to 31.10% active chlorine by tablet weight.

## I. BACKGROUND

**Product Description (as packaged, as applied):** Dilutable concentrate

**Submission type:** Label amendments

**Currently registered efficacy claim(s):** Hospital and healthcare disinfectant (bactericidal, virucidal, fungicidal, tuberculocidal, sporicidal against *Clostridioides difficile*) and food contact surface sanitizer for use on hard, non-porous surfaces. Klorkleen 2 label also makes claims against bacteria in biofilm.

**Requested action(s):** Add electrostatic sprayer application to the labels.

### **Documents considered in this review:**

- Letters from applicant to EPA dated January 27, 2021
- Data Matrices (EPA Form 8570-35) dated January 27, 2021
- Confidential Statements of Formula (EPA Form 8570-4) dated 5/29/2020 & 11/11/2020
- 4 studies (MRID 51440201 - 51440204)
- Studies reviewed in Nov. 2019: 4 studies to support the use of the electrostatic sprayer (MRID Nos.50893001 – 50893004), and 1 study to support the stability claims of the use-solution (MRID No.50463012)
- Proposed labels dated 20210127
- Wetness testing videos

## II. PROPOSED DIRECTIONS FOR USE

### **[HEALTHCARE] {or} [and] [GENERAL] DISINFECTION [PERFORMANCE]**

For SARS-CoV-2, prepare a 1076 ppm solution (4 minute contact time):

6.55 g tablet: 2 tablets to 1 gallon water

1.7 g tablet: 2 tablets to 1 quart water

3.34 g tablet: 1 tablet to 1 quart water

13.1 g tablet: 1 tablet to 1 gallon water

**[General Solution Application with pre-clean:** Apply use solution to pre-cleaned [hard], [non-porous], [inanimate] surfaces with brush, spray device, sponge, cloth, or mop [as appropriate] to wet all surfaces thoroughly. Allow to remain wet for contact time as indicated in the Usage Table, then remove product by wiping with brush, sponge, or cloth or allow to air dry.

### **DIRECTIONS FOR USE WHEN USING AN ELECTROSTATIC SPRAYER DEVICE:**

Prepare solution strength as required, refer to Usage Table for correct doses and contact times; refer to Dilution Chart for solution preparation. Transfer solution to sprayer reservoir or prepare solution in sprayer reservoir as required; refer to sprayer manufacturing instruction. The median droplet size of the spray must be  $\geq 40$   $\mu\text{m}$  in diameter.

Ensure operator is wearing appropriate PPE, including N95 filtering facepiece respirators or half face respirators with N95 filters.

Ensure area is vacated prior to spraying, all bystanders and pets must be removed from the area.

Place the electrostatic spray function in the ON position for electrostatic spray models that have the functionality to toggle ON/OFF.

Spray surfaces as per sprayer instructions from a 1-2 feet [(12-24 inches)] distance. Ensure all other appropriate directions for use as per this product label are also followed.

Ensure surface remains wet for the appropriate contact time, refer to Usage table. Re-apply if necessary.

Allow to air dry.

### III. STUDY SUMMARIES

<b>1.</b>	<b>MRID</b>	51440201 (GLP-compliant, not audited)			
<b>Exp. Start Date</b>		10/22/2020	<b>Study Completion Date:</b>	11/10/2020	
<b>Study Objective</b>		Hard, non-porous surface electrostatic sprayer			
<b>Study Title</b>		ASTM Method to Determine the Virucidal Activity of Liquid, Aerosol, Trigger Spray and Towelettes Disinfectants for Innate, Nonporous Environmental Surfaces			
<b>Testing Lab, Lab Study ID</b>		CREM Co. Labs. Units 1-2, 3403 American Dr., Mississauga, Ontario, Canada L4V 1T4 Study #KRSA200923-01			
<b>Test Method</b>		ASTM E1053; Protocol #KRSA200923-01-FCV			
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Feline calicivirus, strain F9 (ATCC VR-782)			
<b>Indicator Cell Culture</b>		Crandell-Reese Feline Kidney (CRFK), ATCC CCL-94			
<b>Application Method</b>		Sprayed at 2 ft and 4 ft distance using the Protexus PX200ES Electrostatic Sprayer ( $\geq 40 \mu\text{m}$ in droplet size), time sprayed not indicated.			
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Klorsept			
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	P183 (3.41 gm): 1050mg FAC/tablet P114 (3.36 gm): 1050mg FAC/tablet			
	<b>Preparation</b>	2148 ppm FAC: P183: 1 tablet + 488.8 mL water (1050mg FAC/0.4888L) P114: 1 tablet + 1095 mL water (1050mg FAC/0.4888L) Using 400 ppm AOAC Synthetic Hard Water Sample used within 1 hour of preparation			
<b>Soil load</b>		5% FBS			
<b>Carrier type, # per lot</b>		Glass petri dishes, 2 virus rep. per distance per lot			
<b>Test conditions</b>		<b>Contact time</b>	1 min.	<b>Temp</b>	23-25°C
<b>Neutralizer</b>		Dey-Engley (DE) Neutralizing Broth			
<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, etc.)		<p>It is indicated that the sprayer was sprayed enough to remain wet during contact time.</p> <p><b>Gravimetric and Physical Wetness Determination</b></p> <ul style="list-style-type: none"> <li>• For each batch and each distance, three sterile 60×15 mm Petri plates were used to represent the surface to be treated. The weight of each glass was recorded as dry and untreated.</li> </ul>			

	<ul style="list-style-type: none"> <li>• Each Petri plate was located on the predetermined distance from the nozzle of the electro-sprayer (2ft and 4ft)</li> <li>• The plate was sprayed the same way as the efficacy test and left for contact time (1 minutes) at ambient humidity and temperature.</li> <li>• The final weight of each Petri plate was recorded as post-contact time</li> </ul>
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2.	MRID	51440202 (GLP-compliant)			
Experimental Start Date		8/18/2020	Study Completion Date:		11/05/2020
Study Objective		Hard, non-porous surface disinfectant – using electrostatic sprayer			
Study Title		AOAC Germicidal Spray Products as Disinfectant Test			
Testing Lab, Lab Study ID		Microchem Laboratory; Study ID #GLP2436			
Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> (ATCC 15442) <i>Staphylococcus aureus</i> (ATCC 6538)			
Test Method		P2864			
Application Method		Protexus PX200ES Handheld Electrostatic Sprayer; sprayed for 4 seconds from a distance of 2 ft & 4 ft at 45° angle			
Test Substance Preparation	Name/ID	Klorsept			
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	K115: 3240mg FAC/3 tablets M675: 3420mg FAC/3 tablets			
	Preparation	3971 ppm FAC & 4191 ppm FAC: P183: 3 tablet + 816 mL water (3240mg FAC/0.816L) P114: 3 tablet + 816 mL water (3420mg FAC/0.4888L) Using 400 ppm AOAC Synthetic Hard Water			
Soil load		5% FBS			
Carrier type, # per lot		Glass slides, 10 carriers/batch			
Test conditions		Contact time	4 min.	Temp & RH	26-28.1°C & 39-48% RH
Neutralizer		20 mL LEB with 0.2% Sodium Thiosulfate			
Incubation Conditions		48±2 hours & 36±1°C			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)					

3.	MRID	51440203 (GLP-compliant, not audited)		
Experimental Start Date		11/5/2020	Study Completion Date:	12/08/2020
Study Objective		Hard, non-porous surface disinfectant – using electrostatic sprayer		
Study Title		AOAC Germicidal Spray Products as Disinfectants (GSPT): Testing against <i>Staphylococcus aureus</i>		
Testing Lab, Lab Study ID		CREM Co Labs; study no. KRSA200923-SA		
Test organism(s)		<i>Staphylococcus aureus</i> (ATCC 6538)		

<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+			
<b>Test Method</b>		KRSA200923-SA	
<b>Application Method</b>		Protexus PX200ES Handheld Electrostatic Sprayer; sprayed for 20 seconds from a distance of 1 ft, 1.5 ft & 2 ft at 45° angle	
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Klorsept	
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	P183 (3.41 gm): 1050mg FAC/tablet P114 (3.36 gm): 1050mg FAC/tablet	
	<b>Preparation</b>	4296 ppm FAC: P183: 1 tablet + 244.4 mL water (1050mg FAC/0.2444L) P114: 1 tablet + 244.4 mL water (1050mg FAC/0.2444L) Using 400 ppm AOAC Synthetic Hard Water Sample used within 1 hour of preparation	
<b>Soil load</b>		3-part soil load based on ASTM E2197	
<b>Carrier type, # per lot</b>		Glass slides, 10 carriers per lot per distance	
<b>Test conditions</b>		<b>Contact time</b>	<b>Temp &amp; RH</b>
		4 min.	23-25°C & 25-60% RH
<b>Neutralizer</b>		20 mL Lethen broth + 0.2% Sodium Thiosulfate	
<b>Incubation Conditions</b>		48±2 hours & 36±1°C	
<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)			

#### NON-EFFICACY DATA (Wetness testing and previously submitted studies)

<b>4.</b>	<b>MRID</b>	51440204 (GLP)	
<b>Exp. Start Date:</b>		8/20/2020	<b>Study Completion Date:</b> 8/20/2020
<b>Study Objective</b>		Document the surface wetness imparted by simulating use of a ESS device	
<b>Study Title</b>		Gravimetric and Physical Wetness Determination Test	
<b>Testing Lab, Lab Study ID</b>		Microchem Laboratory, Study No. GLP2437	
<b>Test Method</b>		Gravimetric and Physical Wetness Determination Test	
<b>Application Method</b>		Protexus PX200ES cordless electrostatic sprayer at 2ft & 4 ft, time sprayed not indicated ("sprayed until thoroughly wetted")	
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Klorsept	
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Batch K115 & Batch M675 (each tablet reportedly weighs 3.32g)	
	<b>Preparation</b>	Batch K115: 3 tablets + 816 mL water (3971 ppm FAC) Batch M675: 3 tablets + 859.5 mL water (3979 ppm FAC) Diluent: 420 ppm AOAC Synthetic Hard Water	
<b>Soil load</b>		N/A	
<b>Carrier type, # per lot</b>		Glass Petri plate test carriers, 3 carriers per lot per distance	

<b>Test conditions</b>	<b>Contact time</b>	4 min.	<b>Temp &amp; RH</b>	22.6-23.8°C, 43-56%
<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, etc.)	<p>Protocol Amendment #1: Protocol P2865 is hereby amended to clarify that the contact time tested for Klorsept Lots: K115 and M675 will be 4 minutes per Study Sponsor request. This parameter was inadvertently not captured in the protocol.</p> <p>Protocol Deviation: For testing that occurred on 20SUG2020, the Environmental chamber's Relative Humidity was set to 38%. Due to the ambient humidity of the lab and the opening and closing of the chamber between sets, the Relative Humidity inside the chamber rose above the protocol specified range of 35±5% Relative Humidity to 43-56% Relative Humidity. The humidity was above the range specified in the protocol. Meaning with the increased humidity the test substance would have been more likely to not evaporate. This is not thought to have affected the quality of this study as one replicate for lot K115 at 4 feet was dry as the end of the contact time.</p>			

<b>5.</b>	<b>MRID</b>	50893001 (non-GLP)	
<b>Exp. Start Date:</b>	1/29/2018	<b>Study Completion Date:</b>	2/5/18
<b>Study Objective</b>	To determine whether available chlorine concentration of a Klorsept solution is affected when used in conjunction with the Protexus PX200ES cordless electrostatic sprayer.		
<b>Study Title</b>	Report on the examination of Klorsept (EPA Reg. No: 71847-6 in combination with the Protexus PX200ES cordless electrostatic sprayer, when prepared using deionized water and 350-400 Hard water.		
<b>Testing Lab, Lab Study ID</b>	RD148-001R		
<b>Test organism(s)</b> <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+	N/A		
<b>Test Method</b>	N/A		
<b>Application Method</b>	Protexus PX200ES cordless electrostatic sprayer, nozzles 8C and 9C		
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Klorsept	
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Batch J112: 1678.42 mg sodium dichloroisocyanurate/tablet; 1082.58 mg FAC/tablet Batch J337: 1716.94 mg sodium dichloroisocyanurate/tablet; 1107.43 mg FAC/tablet <i>Each tablet is reported to contain 48.21% NaDCC which is equivalent to 31.10% active chlorine by tablet weight.</i>	
	<b>Preparation</b>	Batch J337: A 1 tablet + 1000 mL DI water B 1 tablet + 1000 mL Hard Water C 4 tablets + 1000 mL DI water	

		D 4 tablets + 1000 mL Hard Water Batch J112: E 1 tablet + 1000 mL DI water F 1 tablet + 1000 mL Hard Water J 4 tablets + 1000 mL DI water H 4 tablets + 1000 mL Hard Water			
<b>Soil load</b>		N/A			
<b>Carrier type, # per lot</b>		N/A			
<b>Test conditions</b>		<b>Contact time</b>	N/A	<b>Temp</b>	N/A
<b>Neutralizer</b>		N/A			
<b>Incubation Condition</b>		N/A			
<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, etc.)		<p>The report indicated that the samples were sprayed and collected in a clean glass beaker. These are then analyzed for their NaDCC concentration. Distance from surface sprayed is unknown. Locations of samples collected are unknown. Activation time for concentrations to be reached is not reported.</p> <p>Study conclusion as reported: "When using nozzle 80 or 90 of the Protexus PX200ES electrostatic sprayer, it did not influence the available chlorine concentration of the Klorsept (EPA Reg No: 71847-6) solutions tested when prepared using deionized water or 350 - 400 ppm hard water."</p>			

6.	MRID	50893002		
Exp. Start Date:		2/1/2018	Study Completion Date:	2/4/18
Study Objective		To determine whether available chlorine concentration of a Klorsept solution is affected when used in conjunction with the Protexus PX200ES cordless electrostatic sprayer.		
Study Title		Report on the examination of Klorsept (EPA Reg No: 71847-6) in combination with the Protexus PX300ES cordless electrostatic sprayer, when prepared using deionized water and 350 - 400 ppm Hard water.		
Testing Lab, Lab Study ID		RD148-002R		
Test organism(s) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		N/A		
Test Method		N/A		
Application Method		Protexus PX200ES cordless electrostatic sprayer, nozzles 8C and 9C		
Test Substance Preparation	Name/ID	Klorsept		
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Batch J112: 1678.42 mg sodium dichloroisocyanurate/tablet; 1082.58 mg FAC/tablet Batch J337: 1716.94 mg sodium dichloroisocyanurate/tablet; 1107.43 mg FAC/tablet <i>Each tablet is reported to contain 48.21% NaDCC which is equivalent to 31.10% active chlorine by tablet weight.</i>		

	<b>Preparation</b>	Batch J337: A 3 tablet + 3000 mL DI water B 3 tablet + 3000 mL Hard Water C 12 tablets + 3000 mL DI water D 12 tablets + 3000 mL Hard Water Batch J112: E 3 tablet + 3000 mL DI water F 3 tablet + 3000 mL Hard Water J 12 tablets + 3000 mL DI water H 12 tablets + 3000 mL Hard Water			
<b>Soil load</b>		N/A			
<b>Carrier type, # per lot</b>		N/A			
<b>Test conditions</b>		<b>Contact time</b>	N/A	<b>Temp</b>	N/A
<b>Neutralizer</b>		N/A			
<b>Incubation Condition</b>		N/A			
<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, etc.)		<p>The report indicated that the samples were sprayed and collected in a clean glass beaker. These are then analyzed for their NaDCC concentration. Distance from surface sprayed is unknown. Locations of samples collected are unknown. Locations of samples collected are unknown. Activation time for concentrations to be reached is not reported.</p> <p>Study conclusion as reported: “When using nozzle 80 or 90 of the Protexus PX200ES electrostatic sprayer, it did not influence the available chlorine concentration of the Klorsept (EPA Reg No: 71847-6) solutions tested when prepared using deionized water or 350 - 400 ppm hard water.”</p>			

7.	MRID	50893003		
Exp. Start Date:		9/27/2018	Study Completion Date:	10/1/18
Study Objective		To determine the drying time of unknown Klorsept solutions prepared using hard water (350-400 ppm) over a defined area when sprayed using the Protexus PX200ES electrostatic sprayer.		
Study Title		Report on the examination of drying time of a Klorsept (EPA Reg No: 71847-6) solution prepared using 350 – 400 ppm hard water when sprayed on a ceramic tile using the Protexus PX300ES cordless electrostatic sprayer.		
Testing Lab, Lab Study ID		RD148-006R		
Test organism(s) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		N/A		
Test Method		N/A		
Application Method		Protexus PX200ES cordless electrostatic sprayer, nozzles 8C and 9C		
	Name/ID	Klorsept		



<b>Test Substance Preparation</b>	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Batch K115 & Batch K833 (each tablet reportedly weighs 3.3g) <i>Each tablet is reported to contain 48.21% NaDCC which is equivalent to 31.10% active chlorine by tablet weight.</i>			
	<b>Preparation</b>	Batch K115: A 1 tablet + 1000 mL Hard Water B 4 tablets + 1000 mL Hard Water Batch K833: C 1 tablet + 1000 mL Hard Water D 4 tablets + 1000 mL Hard Water			
<b>Soil load</b>		N/A			
<b>Carrier type, # per lot</b>		N/A			
<b>Test conditions</b>		<b>Contact time</b>	N/A	<b>Temp</b>	N/A
<b>Neutralizer</b>		N/A			
<b>Incubation Condition</b>		N/A			
<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, etc.)		<p>The report indicated the following method for examination of drying time using the Protexus PX200ES electrostatic sprayer: “The Protexus (500 ml) were loaded into the tank of the machine. A ceramic tile of dimensions 24.8 x 60 cm was sprayed from top to bottom with one motion that ensured complete coverage of the tiles in a fine spray. The timer was initiated immediately after spraying the tile. The time at which the tile was completely dry, i.e. no visible moisture remaining, was determined. The experiment was carried out at 20C±5C. Three replicated were carried out for each solution prepared.”</p> <p>Study conclusion as reported: “These data demonstrate that efficacy claims with a contact time ≤10 min according to the Klorsept Master Label (EPA Reg No.: 71847-6) would be achieved with one application spray to a hard, non-porous surface using the PX200ES. However, efficacy claims with a contact time of 30 min as per Klorsept Master Label (EPA Reg No.: 71847-6) would require two staggered applications using the PX200ES in order to reach 30 min contact time.”</p>			

8.	MRID	50893004		
Exp. Start Date:		9/27/2018	Study Completion Date:	10/1/18
Study Objective		To determine the drying time of unknown Klorsept solutions prepared using hard water (350-400 ppm) over a defined area when sprayed using the Protexus PX200ES electrostatic sprayer.		
Study Title		Report on the examination of drying time of a Klorsept (EPA Reg No: 71847-6) solution prepared using 350 – 400 ppm hard water when sprayed on a ceramic tile using the Protexus PX300ES cordless electrostatic sprayer.		
Testing Lab, Lab Study ID		RD148-007R		

<b>Test organism(s)</b> <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		N/A	
<b>Test Method</b>		N/A	
<b>Application Method</b>		Protexus PX200ES cordless electrostatic sprayer, nozzles 8C and 9C	
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Klorsept	
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Batch K115 & Batch K833 (each tablet reportedly weighs 3.3g) <i>Each tablet is reported to contain 48.21% NaDCC which is equivalent to 31.10% active chlorine by tablet weight.</i>	
	<b>Preparation</b>	Batch K115: A 1 tablet + 1000 mL Hard Water B 4 tablets + 1000 mL Hard Water Batch K833: C 1 tablet + 1000 mL Hard Water D 4 tablets + 1000 mL Hard Water	
<b>Soil load</b>		N/A	
<b>Carrier type, # per lot</b>		N/A	
<b>Test conditions</b>		<b>Contact time</b>	N/A
<b>Neutralizer</b>		<b>Temp</b>	N/A
<b>Incubation Condition</b>		N/A	
<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, etc.)		<p>The report indicated the following method for examination of drying time using the Protexus PX200ES electrostatic sprayer: “The Protexus (500 ml) were loaded into the tank of the machine. A ceramic tile of dimensions 24.8 x 60 cm was sprayed from top to bottom with one motion that ensured complete coverage of the tiles in a fine spray. The timer was initiated immediately after spraying the tile. The time at which the tile was completely dry, i.e. no visible moisture remaining, was determined. The experiment was carried out at 20C±5C. Three replicated were carried out for each solution prepared.”</p> <p>Study conclusion as reported: “These data demonstrate that efficacy claims with a contact time ≤10 min according to the Klorsept Master Label (EPA Reg No.: 71847-6) would be achieved with one application spray to a hard, non-porous surface using the PX200ES. However, efficacy claims with a contact time of 30 min as per Klorsept Master Label (EPA Reg No.: 71847-6) would require two staggered applications using the PX200ES in order to reach 30 min contact time.”</p>	

<b>9.</b>	<b>MRID</b>	50463012, Submitted 12/7/17	
<b>Exp. Start Date:</b>	Not available	<b>Study Completion Date:</b>	7/6/2017
<b>Study Objective</b>	To determine if there is any change between the average NaDCC content per tablet in solution 144 hours after initial		

		testing when tablet is in solution of 350ppm – 400ppm hard water.
<b>Study Title</b>		Report on the effect of aging in use-dilution solutions of US Klorsept (EPA Reg No: 71847-6) when prepared using 350 - 400ppm Hard Water
<b>Testing Lab, Lab Study ID</b>		S-02-0196
<b>Test organism(s)</b> <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		N/A
<b>Test Method</b>		N/A
<b>Application Method</b>		
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Klorsept NaDCC Tablets: 1.489g NaDCC/tablet
	<b>Lots</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	5 samples, A, B, C, D, E, from Lot H847 (weighs 3.3 g) <i>Tablet is reported to contain 48.21% NaDCC. Solutions are prepared using hard water between 350 ppm – 400 ppm</i>
	<b>Preparation</b>	Solutions A & B: 4 Klorsept tablets (from same tablet batch) + 1 L hard water: 6680mg/L Solution E: 10 Klorsept tablets (from same tablet batch) + 1 L hard water: 16700mg/L Solutions C & D: 1 Klorsept tablet (from same tablet batch) + 1 L hard water: 1670mg/L
<b>Soil load</b>		N/A
<b>Carrier type, # per lot</b>		N/A
<b>Test conditions</b>	<b>Contact time</b>	3-6 days
	<b>Temp</b>	N/A
<b>Neutralizer</b>		N/A
<b>Incubation Condition</b>		N/A
<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, , etc.)		Study conclusion reported: “The study results show that on day 3 the measured NaDCC concentrations for all five test solutions of Klorsept prepared in hard water remained above their calculated LCLs. On day 4 all but one, and by day 5 two of the initial five test solutions remained above remained above their calculated LCLs.” Only one batch was used.

#### IV. STUDY RESULTS

Virucidal Activity - ESS							
MRID No.	Concentration & contact time	Organism	Results				
				Batch No. P183		Batch No. P114	
w/ 5% FBS, sprayed 2ft. away							
51440201	Diluted to ~2148 ppm FAC w/ 400 ppm AOAC hard water &	Feline calicivirus, strain F9 (ATCC VR-782)	Description	Rep. 1	Rep. 2	Rep. 1	Rep. 2
			Complete Inactivation	10 <sup>0</sup> to 10 <sup>-4</sup> dilutions	10 <sup>0</sup> to 10 <sup>-4</sup> dilutions	10 <sup>0</sup> to 10 <sup>-6</sup> dilutions	10 <sup>0</sup> to 10 <sup>-4</sup> dilutions
			ID <sub>50</sub> /carrier	Not provided		Not provided	
			Log <sub>10</sub> Reduction	≥6.12		≥6.16	

	1-min contact time		<b>Dried Virus Control</b>	Not provided		Not provided	
			<b>Input Control (PFU/mL)</b>	7.3 x 10 <sup>6</sup>		8.2 x 10 <sup>6</sup>	
w/ 5% FBS, sprayed 4ft. away							
51440201	Diluted to ~2148 ppm FAC w/ 400 ppm AOAC hard water & 1-min contact time	Feline calicivirus, strain F9 (ATCC VR-782)	<b>Description</b>	<b>Rep. 1</b>	<b>Rep. 2</b>	<b>Rep. 1</b>	<b>Rep. 2</b>
			Complete Inactivation	10 <sup>0</sup> to 10 <sup>-4</sup> dilutions	10 <sup>-1</sup> to 10 <sup>-4</sup> dilutions	10 <sup>-1</sup> to 10 <sup>-4</sup> dilutions	10 <sup>0</sup> to 10 <sup>-4</sup> dilutions
			ID <sub>50</sub> /carrier	Not provided		Not provided	
			Log <sub>10</sub> Reduction	5.22		≥6.26	
			<b>Dried Virus Control</b>	Not provided		Not provided	
			<b>Input Control (PFU/mL)</b>	7.3 x 10 <sup>6</sup>		8.2 x 10 <sup>6</sup>	

Hard, Non-Porous Surface Disinfectant – ESS							
MRID No.	Contact Time	Organism	No. Carriers Exhibiting Growth/ Total Carriers				Average Carrier Population Control Log <sub>10</sub> (CFU/Carrier)
			2 ft		4 ft		
			Batch #K115	Batch #M675	Batch #K115	Batch #M675	
51440202	4 min.	<i>Staphylococcus aureus</i> (ATCC 6538)	1/10	0/10	6/10	5/10	6.32
		<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/10	0/10	0/10	0/10	6.17

Hard, Non-Porous Surface Disinfectant – ESS									
MRID No.	Contact Time	Organism	No. Carriers Exhibiting Growth/ Total Carriers						Average Carrier Population Control Log <sub>10</sub> (CFU/Carrier)
			1 ft		1.5 ft		2 ft		
			Batch #P183	Batch #P114	Batch #P183	Batch #P114	Batch #P183	Batch #P114	
51440203	4 min.	<i>Staphylococcus aureus</i> (ATCC 6538)	0/10	0/10	0/10	0/10	0/10	0/10	5.93 & 6.17

## Wetness testing

In addition to the efficacy testing, the registrant also conducted wetness testing to demonstrate that the surface remains visibly wet over the duration of the contact time. Videos were provided as well as weight measurements. Wetness was NOT clearly visible in videos.

MRID Number	Average weight (unit unknown), time sprayed unknown Diluted to ~2148 ppm FAC w/ 400 ppm AOAC hard water & 1-min contact time				
	Batch	Weight Type	Rep. 1	Rep. 2	Rep. 3
51440201	Distance @ 2ft				
	Batch P114	Weight #1 (untreated)	6.72	6.72	6.70
		Weight #2 (treated)	8.26	7.85	8.06
		Weight #3 (post contact time)	1.54	1.15	1.35
		Wetness Observation	No visual determination		
	Distance @ 4ft				
	Batch P114	Weight #1 (untreated)	6.69	6.72	6.70
		Weight #2 (treated)	7.29	7.33	7.32
		Weight #3 (post contact time)	0.60	0.61	0.62
		Wetness Observation	No visual determination		
51440201	Distance @ 2ft				
	Batch P183	Weight #1 (untreated)	6.48	6.47	6.45
		Weight #2 (treated)	7.86	7.88	7.87
		Weight #3 (post contact time)	1.38	1.41	1.42
		Wetness Observation	No visual determination		
	Distance @ 4ft				
	Batch P183	Weight #1 (untreated)	6.38	6.39	6.43
		Weight #2 (treated)	7.20	7.57	7.32
		Weight #3 (post contact time)	0.82	1.18	0.89
Wetness Observation		No visual determination			

MRID Number	Average weight (g), time sprayed unknown Diluted to 3971 ppm & 3979 ppm FAC w/ 400 ppm AOAC hard water & 4-min contact time				
	Batch	Weight Type	Rep. 1	Rep. 2	Rep. 3
51440204	Distance @ 2ft				
	Batch K115	Weight #1 (untreated)	89.64	102.67	90.41
		Weight #2 (treated)	90.78	103.99	91.74
		Weight #3 (post contact time)	90.51	103.60	91.42
		Remaining test sub weight	0.87	0.93	0.01
		Wetness Observation	Wet	Wet	Wet
	Distance @ 4ft				
	Batch K115	Weight #1 (untreated)	105.37	105.88	104.02

		Weight #2 (treated)	105.55	106.10	104.22
		Weight #3 (post contact time)	105.40	105.92	104.03
		Remaining test sub weight	0.03	0.04	0.01
		Wetness Observation	Wet	Dry	Wet
51440204	<b>Distance @ 2ft</b>				
	Batch M675	Weight #1 (untreated)	85.33	90.01	87.85
		Weight #2 (treated)	86.39	91.18	89.09
		Weight #3 (post contact time)	86.19	90.98	88.87
		Remaining test sub weight	0.86	0.97	1.02
		Wetness Observation	Wet	Wet	Wet
	<b>Distance @ 4ft</b>				
	Batch M675	Weight #1 (untreated)	91.32	89.55	85.39
		Weight #2 (treated)	91.40	89.66	85.52
		Weight #3 (post contact time)	91.34	89.58	85.41
		Remaining test sub weight	0.02	0.03	0.02
		Wetness Observation	Wet	Wet	Wet

MRID 50893003: Average drying time of Protexus PX200ES on ceramic tile with 2 nozzle sizes				
Batch	Contact time	Solution (ppm FAC)	Nozzle	Average drying time (min.)
K115	30 sec. – 1 min.	1093.22	8C	26.97
			9C	21.12
		4259.30	8C	22.72
			9C	24.04
K833	30 sec. – 1 min.	1093.22	8C	23.64
			9C	24.64
		4294.82	8C	24.72
			9C	18.53
MRID 50893004: Average drying time of Protexus PX300ES on ceramic tile with 2 nozzle sizes				
Batch	Contact time	Solution (ppm FAC)	Nozzle	Average drying time (min.)
K115	30 sec. – 1 min.	1093.22	8C	28.44
			9C	26.87
		4294.82	8C	24.77
			9C	23.83
K833	30 sec. – 1 min.	1093.22 & 1086.13	8C	20.56
			9C	24.34
		4259.30	8C	26.56
			9C	23.17

MRID #50463012: Effect of time (aging) on measured concentration of NaDCC and pH in end use dilutions of Klorsept prepared with 350-400 ppm							
Lot #/Manufacturing date: 6/22/2017	Sample	Composition of solution	Day	pH	Approx. ppm of solution based on assay results (ppm)	LCL for specific dilution based on CSF (ppm)	Difference from day 0 (%)
H847	A	Hard water + 4 Klorsept tablets	0	5.83	4294.83	3825.22	--
			3	6.06	4085.04		5.79
			4	6.12	3922.12		8.68
			5	6.19	3780.14		11.98
			6	6.17	3815.64		11.16
	B	Hard water + 4 Klorsept tablets	0	5.85	4454.60		--
			3	6.12	4206.08		5.58
			4	6.11	4028.62		9.56
			5	6.14	4090.72		8.17
			6	6.14	4037.49		9.36
	C	Hard water + 1 Klorsept tablets	0	6.29	1061.28	956.31	--
			3	6.37	993.84		6.35
			4	6.86	990.29		6.69
			5	6.74	986.75		7.02
			6	6.74	933.50		12.04
	D	Hard water + 1 Klorsept tablets	0	6.27	1089.68		--
			3	6.64	1047.09		3.91
			4	6.97	1004.49		7.82
			5	7.11	968.00		11.07
			6	7.12	937.06		14.01
	E	Hard water + 10 Klorsept tablets	0	5.70	10541.82	9563.06	--
			3	5.93	9619.01		8.75
			4	5.94	9562.74		9.26
			5	5.95	9530.26		9.60
			6	5.95	9299.55		11.78

## V. STUDY CONCLUSIONS

MRID	Objective	Surface	Application Method & Dilutions	Spray & contact times	Soil Load	Organism(s)	Distance	Data support tested condition(s)?
51440201	Virucidal Activity – Electrostatic Sprayer	Hard, non-porous surfaces (petri dish)	Diluted to ~2148 ppm FAC w/ 400 ppm AOAC hard water	1 min. contact time (spray time unknown)	5% FBS	Feline Calicivirus ATCC VR-782	2 ft.	No*
							4 ft.	No*
51440202	Bactericidal Activity – Electrostatic Sprayer	Hard, non-porous surfaces (glass slides)	Diluted to 3971 ppm FAC w/ 364-380 ppm AOAC hard water	4 min. contact time; sprayed 4 sec. @ 45° angle	5% FBS	<i>Staphylococcus aureus</i> (ATCC 6538)	2 ft.	No
							4 ft.	No
						<i>Pseudomonas aeruginosa</i> (ATCC 15442)	2 ft.	Yes
							4 ft.	Yes
51440203 (retest for <i>S. aureus</i> )	Bactericidal Activity – Electrostatic Sprayer	Hard, non-porous surfaces (glass petri dish)	Diluted to 4296 ppm FAC w/ 400 ppm AOAC hard water	4 min. contact time; sprayed 20 sec.	3-part soil	<i>Staphylococcus aureus</i> (ATCC 6538)	1 ft.	Yes
							1.5 ft.	Yes
							2 ft.	Yes
51440201	Wetness testing	Hard, non-porous surfaces (glass petri dish)	Diluted to ~2148 ppm FAC w/ 400 ppm AOAC hard water	1 min. contact time (spray time unknown)	N/A	N/A	2 ft.	No*
							4 ft.	No*
51440204	Wetness testing	Hard, non-porous surfaces (glass petri dish)	3971 & 3979 ppm FAC w/ 400 ppm AOAC hard water	4 min. contact time (spray time unknown)	N/A	N/A	2 ft.	Yes
							4 ft.	Yes

\*additional information needed, see detail in comments below



## **VI. LABEL COMMENTS**

### **Proposed Labels Ver. 18 for Klorsept 20210127 & Ver. 9 for Klorkleen 2 20210127**

1. The proposed label claims that the products, Klorsept (Reg. #71847-6) & Klorkleen 2 (Reg. #71847-7), when used with an electrostatic sprayer as directed from 1-2 ft. distance on visibly cleaned hard, non-porous surfaces when diluted according to the dilutions for disinfection with virucidal activity for the indicated contact times for viruses on the labels are not acceptable for the following reasons:

- a. Per the 810.2200, the result reports for the viral study with MRID #51440201 should be calculated as follows:
- Section (G)(6)(vi) indicates that the 50% infectious dose (ID<sub>50</sub>) values (for all carriers) for each assay should be calculated by using an appropriate statistical method (e.g., Reed and Munch, Most Probable Number, Spearman-Kärber).
  - Section (G)(6)(vii) indicates that The test results should be reported as the log reduction of the virus (ID<sub>50</sub> of the virus control carriers less the ID<sub>50</sub> of the test carriers) as calculated by an appropriate statistical method (e.g., Reed and Munch, Most Probable Number, Spearman-Kärber). The log reduction calculation should take into consideration the level of cytotoxicity and neutralization. Results should be reported per assayed volume and per carrier/surface.

These calculations should be provided for further evaluation.

- b. The wetness testing to substantiate the concentration at 2153 ppm FAC requires additional information for evaluation (MRID #51440201 and accompanying wetness testing videos):
- Visual wetness determination was not provided in the study report.
  - The unit of weight was not provided in the study report.
  - The time of spraying was not provided in the study report. Videos showed spraying for longer than acceptable. Please confirm the spraying time in the videos.
  - The videos performed in the laboratory did not specify the spraying distance, spraying time, nor did they provide a visualization on the wetness of each carrier.

Please provide the requested information for further evaluation.

- c. If/when these data gaps are addressed, please note that the concentration and contact time tested in the virucidal efficacy and wetness study only support the concentration of 2153 ppm or above and the contact time of 1 minute. Disclaimers/prohibitory statements should be added to the labels to take these into consideration. As noted in the technical screen deficiency back in February 2021, in order to bridge/confirm organisms under disinfection with bactericidal and disinfection with virucidal activity, the following conditions should be tested for labels with multiple dilution rates and contact times:

- Confirmatory efficacy tests using the electrostatic sprayer should be conducted using the most conservative conditions (i.e., most diluted concentration and shortest contact time) claimed on the label, and wetness testing should be conducted using the most diluted concentration and longest contact time claimed on the label. This is to ensure that the bridged organisms at their corresponding dilutions and contact times are also inactivated and that surfaces stay wet for the duration of the contact times.
2. The proposed label claims that the products, Klorsept (Reg. #71847-6) & Klorkleen 2 (Reg. #71847-7), when used with an electrostatic sprayer as directed from 1-2 ft. distance on visibly cleaned hard, non-porous surfaces when diluted according to the dilutions for disinfection with bactericidal activity for the indicated contact time for bacteria on the labels are not acceptable for the following reasons:
- a. Please revise the distance for electrostatic sprayer in the directions for use to indicate only at 2 ft. distance. Efficacy data for *Pseudomonas aeruginosa* did not test at the minimum distance claimed (1 ft.).
  - b. The videos performed in the laboratory did not specify the spraying distance nor do they show clear visualization of the wetness on each carrier using the wipes.
  - c. If/when these data gaps are addressed, please note that the concentration and contact time tested in the bactericidal efficacy and wetness studies only support the concentration of 4306 ppm and the contact time of 4 minute. Disclaimers/prohibitory statements should be added to the labels to take these into consideration. As noted in the technical screen deficiency back in February 2021, in order to bridge/confirm organisms under disinfection with bactericidal and disinfection with virucidal activity, the following conditions should be tested for labels with multiple dilution rates and contact times:
    - Confirmatory efficacy tests using the electrostatic sprayer should be conducted using the most conservative conditions (i.e., most diluted concentration and shortest contact time) claimed on the label, and wetness testing should be conducted using the most diluted concentration and longest contact time claimed on the label. This is to ensure that the bridged organisms at their corresponding dilutions and contact times are also inactivated and that surfaces stay wet for the duration of the contact times.
3. Please remove all references to electrostatic sprayer application until additional information is provided for evaluation.